

RESEARCH FINANCIAL CONFLICT OF INTEREST STATEMENT

What is Conflict of Interest?

A financial conflict or perceived conflict of interest occurs when any financial arrangement, situation or action affects or is perceived to exert inappropriate influence on the design, review, conduct, results or reporting of research activities or findings. Concerns related to conflicts of interest have increased as the relationships of investigators with private corporations, pharmaceutical companies, and outside institutions have become more complex. These concerns are based on the potential effects the conflicts may have on the actual or perceived quality of the research and the treatment of research participants.

The main conflict of interest statute in the federal criminal code, 18 U.S.C. § 208, prohibits all VA employees (full-time, part-time, WOC, and IPA) from participating personally and substantially, as part of their official duties, in any particular matter, including research, that directly and predictably affects their own financial interests or any financial interests imputed to them. Financial interests that are imputed to a VA employee include the financial interests of a spouse; minor child; general partner; an organization in which the VA employee serves as an officer, director, trustee, general partner, or employee; or an organization with which the VA employee is negotiating or has an arrangement for prospective employment. Imputed financial interests are treated as if they were the VA employee's own financial interests for purposes of this prohibition.

In addition to the disclosures required in the attached form, all VA employees are subject to the criminal conflict of interest statutes at Title 18, United States Code (U. S.C.) Chapter 11, and the Executive Branch Standards of Conduct at Title 5 Code of Federal Regulations (CFR), Part 2635. Violation of these provisions may be sanctioned by civil and criminal penalties, as well as employment-related discipline such as removal or suspension.

Getting Ethics Advice

VA Regional Counsels and the Assistant General Counsel for Professional Staff Group III (023), the designated agency ethics official, maintain ethics expertise and provide ethics counseling services to employees. Employees with questions regarding these requirements are encouraged to contact their respective Regional Counsels. Those in VA Central Office should contact the Assistant General Counsel for Professional Staff Group I (023).

NOTE: Question 7. Publicly Traded Companies: a) You must aggregate the interests of yourself, spouse and dependent children when determining if you have reached the threshold amount; b) If your research involves human subjects, THE THRESHOLD AMOUNT IS \$10,000 (not \$15,000).



RESEARCH FINANCIAL CONFLICT OF INTEREST STATEMENT

This completed form may only be reviewed by personnel on an "as needed" basis when required by the responsibilities of their position.

This form must be completed and submitted by each principal investigator, co-principal investigator, investigator and collaborator. The information will be used to determine if there is a perceived or real financial conflict of interest or if there is the potential for such financial conflicts of interest. The form will only be reviewed by persons on a need-to-know basis. The completed and signed document must be submitted to the financial conflict of interest (FCOI) committee.

Note: if any questions below are answered in the affirmative, the conflicts must be managed with the assistance of the VA Regional Counsel or, in Central Office, the Office of the General Counsel. Further, even if no question is answered in the affirmative, your financial holdings or arrangements may still pose a conflict of interest within the meaning of Chapter 11 of Title 18, United States Code, and the Executive Branch Standards of Conduct at 5 C.F.R. Part 2635. Compliance with the provisions in this handbook will not necessarily satisfy the requirements of these criminal and regulatory conflict of interest provisions. If you have questions regarding these requirements, you can contact your local Regional Counsel for assistance. If you are located in Central Office, you can contact the Assistant General Counsel for Professional Staff Group III (023).

LAST NAME- FIRST NAME- MIDDLE INITIAL

SECTION I

INSTRUCTIONS: If any of the following questions are answered in the affirmative you will be expected to provide such information as required to determine whether the financial holdings or business interests in question are sufficiently small that the potential conflict of interest should not preclude funding of or conducting VA research.

1. INCOME AND COMPENSATION. Do you or your spouse or dependent child receive income or other compensation for services (to include consulting fees, honoraria, gifts, and/or in kind compensation) from a single entity (or a group of affiliated entities) that when aggregated for you, your spouse and dependent child has in the prior year exceeded \$10,000 and/or is expected to exceed \$10,000 in the next 12 months? *NOTE:* An entity is any for profit organization, institution, corporation, partnership, or other entity (other than a Federal agency or university affiliate) that does or seeks to do business in an area related to your present research or research you are currently planning.

☐ YES

☐ NO

2. PATENTS. Do you or your spouse, or dependent child, or an organization (other than a Federal agency) in which you are an officer, director, trustee, general partner or employee own any patents or provisional patents that are related to your present research or research you are currently planning or to any of your other research duties?

☐ YES

☐ NO

3. COPYRIGHTS. Do you or your spouse, or dependent child, or an organization (other than a Federal agency) in which you are an officer, director, trustee, general partner or employee hold any copyrights that are related to your current research or research you are currently planning?

☐ YES

☐ NO

4. ROYALTIES. Do you or your spouse, or dependent child, or any organization in which you are an officer, director, trustee, general partner or employee receive any royalty payments or non-monetary considerations from a business or organization that does business in an area related to your current research or research you are currently planning?

☐ YES

☐ NO

5. BUSINESS CONCERNS. Do you or your spouse, or dependent child, or an organization in which you are an officer, director, trustee, general partner or employee have any business or financial relationship with any person or organization for which the results of your current research or research you are currently planning may be reasonably expected to affect the development or marketing of that person's or organization's product or service?	<input type="checkbox"/> YES
	<input type="checkbox"/> NO
6. NON-PUBLICLY TRADED COMPANIES. Do you or your spouse, dependent child, or any organization in which you are an officer, director, trustee or general partner own or have any equity interests by way of stock ownership or stock options in a non-publicly traded company that does business in an area that is related to your present research or research you are currently planning?	<input type="checkbox"/> YES
	<input type="checkbox"/> NO
7. PUBLICLY TRADED COMPANIES. Do you or your spouse, dependent child, or any organization in which you are an officer, director, trustee or general partner own or have an equity interest valued at more than \$15,000 (stock ownership or stock options, etc.) in a publicly traded company that does business in an area that is related to your present research or research you are currently planning? <i>NOTE: This does not include stock that is controlled through a widely diversified mutual fund or a blind trust.</i>	<input type="checkbox"/> YES
	<input type="checkbox"/> NO
IF YOU HAVE CHECKED NO TO ALL QUESTIONS CHECK THIS BOX <input type="checkbox"/>	
I certify that, to the best of my knowledge and belief, all of the information on this disclosure is true, correct, complete, and made in good faith. I understand that false or fraudulent information on this disclosure may be grounds for not accepting the research proposal and may be punishable by fine or imprisonment (U.S. Code, Title 18, section 1001).	
Signature of Investigator	Date
SECTION II: SUPPLEMENTAL INFORMATION	
1. INCOME & COMPENSATION. If you answered yes in Section I, explain source, and reason for compensation: (NOTE: the FCOI committee may request information on the values or amounts.)	
2. PATENTS. If you answered yes in Section 1 provide additional information below. For additional patents provide same information on a separate sheet and attach.	
2A. PATENT NUMBER:	
2B. IS THIS A PROVISIONAL PATENT?	YES <input type="checkbox"/> NO <input type="checkbox"/>
2C. DATE OF PATENT:	2D. PERIOD COVERED:
2E. TITLE OF PATENT:	
2F. PROJECTED ROYALTIES BY YEAR:	
2G.HAVE ANY ACTIVE OR PENDING LICENSE AGREEMENTS BEEN ISSUED? (If yes, attach a copy of each license.)	YES <input type="checkbox"/> NO <input type="checkbox"/>

SECTION II: SUPPLEMENTAL INFORMATION Continued

3. COPYRIGHTS. If you answered yes in Section 1, provide additional information below.

4. ROYALTIES. If you answered yes in Section 1, provide additional information below.

4A. SOURCE:

4B. AMOUNT:

5. BUSINESS CONCERNS. If you answered yes in Section I, provide additional information below including specific information on the business and on the development or marketing of the product or service.

6. NON-PUBLICLY TRADED COMPANIES. If you answered yes in Section I, provide additional information below.

☐ YES

VALUE OF STOCK/STOCK OPTIONS: Does this value represent more than a 5% ownership of the company?

☐ NO

7. PUBLICLY TRADED COMPANIES. If you answered yes in Section I, provide additional information below.

☐ YES

VALUE OF STOCK/STOCK OPTIONS: Does This Value Represent More Than A 5% Ownership Of The Company?

☐ NO

PRIVACY ACT STATEMENT

Title I of the Ethics in Government Act of 1978 (5 U.S.C. App.), Executive Order 12674, and 5 CFR 2634, Subpart I, of the Office of Government Ethics regulations require the reporting of this information. The primary use of the information on this form is for review by the VHA Conflict of Interest Committee to determine compliance with applicable Federal conflict of interest laws and regulations and the impact of any real or perceived financial conflicts of interest on VA research. Additional disclosures of the information in this report may be made:

- (1) to other VA research review committees and VA officials responsible for the approval or funding of research protocols;
- (2) if there is an indication of a violation or potential violation of law, whether civil, criminal or regulatory in nature and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, to the appropriate Federal, State or local agency charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto;
- (3) to qualified reviewers for their opinion and evaluation of a proposal as part of the application review process when a proposal is submitted for funding;
- (4) to the National Archives and Records Administration of the General Services Administration in records management inspections; and
- (5) to the Department of Justice (DOJ) upon official request in order for VA to respond to pleadings, interrogatories, orders or inquiries from DOJ and to supply to DOJ the information to enable DOJ to represent the U.S. Government in any phase of litigation or in any case or controversy involving VA.

Failure to file or report information or the falsification of required information may subject you to disciplinary action by the VA or other appropriate authority. This may include limitation on or revocation of the privilege to conduct VA-approved research. It may also be subject to criminal prosecution.